Petition

81-1449

FILED
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ALEXANDER L. STEVAS,
CLERK

IN THE SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1981

NO: _____

LORA E. LOGE, and
ROGER S. LOGE, her husband,

Petitioners,

V.

UNITED STATES OF AMERICA and
UNKNOWN EMPLOYEES OF THE
DEPARTMENT OF HEALTH, EDUCATION
AND WELFARE,

Respondents.

PETITION FOR WRIT OF CERTIORARI TO THE COURT OF APPEALS FOR THE EIGHTH CIRCUIT

Walter S. Kyle
Attorney for the Petitioners
P. O. Box 350305
Ft. Lauderdale, Florida 33335-0305
Telephone: (305) 987-6767

QUESTIONS PRESENTED FOR REVIEW

1) Where, as alleged in the Amended Complaint, Petitioner, Lora Loge, was rendered a permanent paraplegic through her involuntary exposure to a type of untested, live poliovirus vaccine and where her exposure to that particular type of live poliovirus was intentionally caused by and was pursuant to a plan of the Respondents, to immunize people, such as Lora Loge, without their knowledge, consent or volition, have Petitioners stated a cause of action against the Respondents for violations of their constitutional rights to privacy and security under the jurisdictional grant of 28 U.S.C. § 1331(a).

2) Did the District Court for the Western District of Arkansas and the Court of Appeals for the Eighth Circuit err in holding that the shed-virus type of Live

Polio Vaccine, to which Petitioner, Lora Loge, was involuntarily exposed, did not need to be tested for safety under pertinent regulations relating to Live, Poliovirus Vaccine safety in spite of the fact, as alleged, that the Respondents intended the shed-virus vaccine to be an integral part of this nations polio immunization program.

PARTIES: The caption of the case in this Court contains the names of all parties.

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REPORTS OF LOWER COURT'S OPINIONS

1) Opinion of District Court:
494 F.Supp. 883 (1980)

2) Opinion of Eighth Circuit
Court of Appeals:
662 F.2d 1268 (1981)

GROUNDS FOR JURISDICTION OF THE UNITED STATES SUPREME COURT

The Court of Appeals for the Eighth Circuit filed its opinion and entered its judgment on November 6, 1981, at approximately 9:00 A.M.

The statutory provision believed to confer jurisdiction on this Court is 28 U.S.C. § 1254(1).

CONSTITUTIONAL PROVISIONS, STATUTES AND REGULATIONS INVOLVED IN THIS CASE*

1) Amendments 1, 4, 5 and 9 to the Constitution of the United States ------ A-71, A-72

2) 28 U.S.C. §§ 1254(1) ---- 1, 10, A-79

3) 28 U.S.C. §§ 1331(a) ---- i, 9, A-79

4) 28 U.S.C. §§ 1346(b) ---- 9, 10, 19, 20 A-72

5) 28 U.S.C. §§ 2680(a) ---- 19, A-73

6) 42 U.S.C. §§ 262(d) ---- 2, 3, 4, 18 A-74

7) 21 C.F.R. §§ 600-630 ---- 2, 3, 6, 7 18, 19, A-78

8) 42 C.F.R. §§ 73 --------- 4, 19, A-76

*REPRODUCED IN THE APPENDIX

FACTS MATERIAL TO CONSIDERATION OF QUESTIONS PRESENTED

The material facts, as construed by the Court of Appeals, indicate the following:

In June 1963, the Secretary of Health, Education and Welfare licensed Lederle Laboratories to manufacture Orimune-a trivalent, live, oral poliovirus vaccine. See 42 U.S.C. §§ 262(a); 21 C.F.R. §§ 630.10(a). Orimune is composed of all three Sabin strains of live poliovirus corresponding to the three different types of polio (known as Types 1, 2, and 3), thus the designation "trivalent." A characteristic of live Sabin polio vaccines such as Orimune is that not only is the vaccine's recipient immunized from polio, but unimmunized persons who come into close contact with the recipient also

are immunized through a shed virus which spreads from the recipient to the "contact." Because Sabin strains contain the live polio virus, there is a risk that either a recipient or a contact could develop polio. Accordingly, the Secretary has promulgated regulations pertaining to the safety and potency of these strains which serve to protect susceptible persons from contracting the disease.[1] Drug manufacturers must prove their product's conformity to these regulations before the Secretary will issue a license to manufacture. 42 U.S.C. § 262(d).

A risk free alternative to inoculation with the live Sabin vaccine is the Salk vaccine in which the virus is killed so that the recipient cannot contract polio nor can the recipient shed a live virus

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[1] 21 C.F.R. §§ 630.10-630.18. At the time of Lederle's licensing, these regulation were found at 42 C.F.R. § § 73.110-73.118.

to unimmunized contacts. But the Secretary has promoted the use of risk-bearing live, vaccines because they are able to effect total immunization of the public through transmission of the shed virus with less than total inoculation.

Mrs. Loge was exposed to the shed virus in 1976 after a doctor inoculated her infant son Todd with Orimune. Within one month after her son's inoculation, Mrs. Loge was stricken with a vaccine-associated case of poliomyelitis, Type 2. As a result, she is now a paraplegic. The Loges brought suit in the United States District Court for the Western District of Arkansas against the United States and unknown employees of the Department of Health, Education and Welfare. The district court liberally construed their amended complaint to state the following claims against the United States under the Federal Tort Claims Act based on the Secretary of Health,

Education and Welfare's negligence in:

(1) licensing all spread virus vaccines including Orimune, without requiring the manufacturer to produce the information required by 21 C.F.R. § 630.10(b)(2);

(2) licensing all live oral poliovirus vaccines without testing their safety for persons in close proximity to those inoculated, but who themselves have not received the vaccine;

(3) licensing all live oral poliomyelitis vaccines when the Secretary knew that the viruses reproduced within the inoculated person would not pass the safety requirements applicable to the viruses contained within the inoculant;

(4) licensing Types 1, 2, and 3 of the Sabin poliomyelitis live vaccine without establishing that it was free from harmful effect on individuals who

had been determined to be particularly susceptible to the disease;

(5) licensing Orimune without issuing regulations designed to insure its continued safety;

(6) failing to apply the review procedures set forth in 21 C.F.R. §§ 601.25;

(7) failing to enact regulations which would assure the safety of trivalent oral polio vaccine as defined in 21 C.F.R. §§ 600.3(p);

(8) subjecting Mrs. Loge to shed virus inoculation without her knowledge or consent;

(9) failing to approve a stronger package insert warning about adverse reactions;

(10) failing to use due care in approving Lederle Lot No. 451-162-the vaccine lot from which Todd Loge received his inoculation-of the

trivalent, live, oral polio vaccine. R. 73-74.

Additionally the Loges pleaded that under Bivens v. Six Unknown Federal Narcotics Agents, 403 U.S. 388, 91 S.Ct. 1999, 29 L.Ed.2d 619 (1973) and Carlson v. Green, 446 U.S. 14, 100 S.Ct. 1468, 64 L.Ed.2d 15 (1980), they have a cause of action for damages directly under the Constitution for deprivation of Mrs. Loge's rights under the Fifth Amendment and her right of privacy. They claim that the government knowingly deprived Mrs. Loge of these rights in pusuing a national policy to vaccinate everyone against polio, including persons such as Mrs. Loge who did not voluntarily submit to the immunization program.

BASIS FOR FEDERAL JURISDICTION IN COURT OF FIRST INSTANCE

The facts underlying this cause of action occurred on or about August 21, 1976. An administrative claim was timely presented to the appropriate Federal Agency, the Department of Health, Education and Welfare, on July 20, 1978, and that claim was denied on July 7, 1979.

This lawsuit was then filed in the Federal District Court for the Western District of Arkansas on November 29, 1979 with jurisdiction under 28 U.S.C. § 1346(b).

After the Defendant filed a Motion to Dismiss, the Complaint was amended on or about June 13, 1980. The Amended Complaint was a restatement of the original Complaint and added unknown Employees of the Department of Health, Education and Welfare as Defendants and alleged jurisdiction over that claim pursuant to 28 U.S.C. § 1331 in addition to the jurisdiction of

28 U.S.C §§ 2671, (1346(b) et. seq.)

After oral argument the District Court dismissed the Complaint and its amendments on July 28, 1980. (494 F.Supp. 883) (1980). A timely appeal was filed on September 18, 1980 to the Court of Appeals for the Eighth Circuit pursuant to Rule 4 of the Federal Rules of Appellate Procedure. The Court of Appeals affirmed the District Court, in part and reversed in part. The opinion and judgment of the Court of Appeals was entered November 6, 1981. (662 F.2d 1268) (1981).

This petition for a Writ of Certiorari was timely filed pursuant to 28 U.S.C. 1254 (1) on or before February 4, 1982.

ARGUMENT

1) As to the first question presented, the Petitioners assert that an important interpretation of the federal constitution has been made by the Court of Appeals for the Eighth Circuit, and even though this United States Supreme Court has not been directly presented with the question before, Petitioners feel that the decision of the Court of Appeals is contrary to the spirit if not the letter of the Constitution and that it erred in dismissing Petitioners claim which arose directly under the Constitution.

In a cause of action predicated upon the same fundamental concepts as Bivens v. Six Unknown Federal Narcotics Agents, 403 U.S. 388, 91 S.Ct. 1999, 29 L.Ed. 619 (1973), and Carlson v. Green, 446 U.S. 14, 100 S.Ct. 1468, 64 L.Ed.2d 15 (1980), the Petitioners request this

court to determine that the unknown doctors, agents and employees of the Department of Health, Education and Welfare can be held personally responsible for their decision to promote and participate in a polio immunization program which subjected people such as Petitioner, Lora Loge, to an involuntary inoculation with and unsuspecting exposure to a potentially lethal, untested, live viral agent, which agent caused the permanent paralysis of the Petitioner.

It has been held that there are certain areas or zones of privacy into which the government may not intrude absent a compelling interest. (Roe v. Wade, 410 U.S. 113, 163 (1973)).

> "The Constitution does not explicitly mention any right of privacy. In a line of decisions, however, going back perhaps as far as Union Pacific R. Co. v. Botsford, 141 U.S. 250, 251 (1891), the Court has recognized that a right of

> personal privacy, or a guarantee of certain areas or zones of privacy, does exist under the Constitution." Id. @ 152.

The fact that the government may force immunizations in certain cases is not questioned (Jacobson v. Mass., 197 U.S. 11 (1905)), however, Jacobson held that such an immunization could be refused were it contraindicated in the particular patient.

> "we are not inclined to hold that the statute establishes the absolute rule that an adult must be vaccinated if it be apparent or can be shown with reasonable certainty that he is not at the time a fit subject of vaccination..."

The live, oral poliovirus vaccine is contraindicated for adults, there is no statutory authority requiring such immunization and adult immunization with the Sabin vaccine has not been recommended since 1964.

The shed-virus strains of the Sabin

vaccine, which infected Petitioner according to Respondents records, are even more dangerous and neurovirulent than the manufacturers dose of the product ORIMUNE.

Neither the Sabin vaccine nor the shed-virus strains of that vaccine have ever been tested for safety under controlled field studies.

Petitioners feel that the above factors are pertinent in determining whether to grant the Writ of Certiorari because of the threshold analysis that need be made. That analysis would involve a balancing of the governmental interest in causing such an involuntary immunization against the Petitioner's right to privacy and freedom from governmental intrusion.

In the case at bar, where there was no statutory authority requiring the immunization, where the immunization was caused by an untested and unsafe viral agent and where an absolutely safe alternative, the

Salk vaccine, existed which could have safely immunized the Petitioner, the Petitioners assert that their rights to privacy and security as guarded by the Penumbra of the Bill of Rights override any conceivable governmental interest in subjecting Lora Loge to the potentially lethal shed-virus strains of Sabin vaccine.

It is imperative that this matter be resolved by this Court for the reasons above stated and that the polio immunization program is continuing to subject people to the same type of involuntary exposure, day after day. That the governments doctors are emminently aware of this law-suit and that a failure to resolve it now might lead them to believe that their decisions, whatever they be, are beyond reproach.

Gene splicing and genetic engineering are producing life forms, at this very moment, which God did not see fit to put

on this planet. Please grant this Writ of Certiorari and reverse the holding of the Court of Appeals that Petitioners had not stated a claim for a violation of their Constitutional rights. Give the Petitioners the opportunity to prove their allegations at trial and let the grant of this Petition serve as a warning to those who control such genetic mutation programs, that unfettered discretion will not go unquestioned, at least not in this Country, under our Constitution.

2) The second question presented herein is a critical part of the first.

The Court of Appeals held that since no statute specifically required the "shed-virus" vaccine to be tested, then the Petitioners' allegations that the government's failure to test that vaccine was discretionary and a cause of action under the Federal Tort Claims Act barred

by the discretionary function exemption to the Federal Tort Claims Act.

Petitioners disagree and request that the court review and reverse this holding.

The term "shed-virus" vaccine was coined by the undersigned attorney in order to describe a type of vaccine strain used in the government's polio immunization program. The "shed-virus" should clearly be tested even under the most rigid interpretation of the safety statutes.

The safety statutes were written to protect the vaccinees from their immunizations, not to immunize the vaccinators from liability. The factor that is most important in determining whether the "shed-virus" vaccine should have been tested is its intended use in the overall program and that use is clearly alleged as substantial, hence Petitioners assert it should have been tested under the following regulatory provisions which

were duly promulgated pursuant to 42 U.S.C. § 262.

21 C.F.R. § 600.3 defines: Products

21 C.F.R. § 600.3(g) to include "biological products" and a "Biological Product"

21 C.F.R. § 600.3(h) means any virus, therapeutic serum, toxin, anti-toxin, or analogous product applicable to the prevention, treatment or cure of diseases or injuries of man. (i) a virus is interpreted to be a product containing the minute living cause of an infectious disease ...

21 C.F.R. § 600.3(h)(4) ... A product is analogous (i) to a virus if prepared from or with a virus or agent actually or potentially infectious.

21 C.F.R. § 600.3(j) ... A product is deemed "applicable to the prevention, treatment, or cure of diseases or injuries of man" irrespective of the mode of administration or application recommended.

21 C.F.R. § 630.10(b)(2) mandates that -

Poliovirus strains shall not be used in the manufacture of Poliovirus Vaccine, Live, Oral, unless,

> (i) data are submitted to the Commissioner of Food and Drugs which establish that each such strain is free of harmful effect upon administration in the recommended dosage to at least one million people susceptible to poliomyelitis.

As used in the Amended Complaint and as defined in 21 C.F.R. §§ 600.3(p): The word "safety" means:

> "relative freedom from harmful effect to persons affected, directly or indirectly, by a product when prudently administered."

Petitioners assert, therefore, that the decisions of the lower courts were in error in holding that the above statute (and their progenitor 42 C.F.R. §§ 73) were not mandatory and that the cause of action for failure to test the "shed-virus" strains of the Sabin vaccine was barred by the discretionary function exemption 28 U.S.C. §§ 2680(a), of the Federal Tort Claims Act (FTCA) 28 U.S.C. § 1346.

Although the Federal Tort Claims Act is not the proper medium to challenge ones unconstitutional acts - Petitioners assert that once the veil of sovereign immunity has been lifted by the Federal Tort Claims Act, that the government cannot assert an unconstitutional act as discretionary under 28 U.S.C. 2680(a) in order to bar liability.

This lawsuit is for negligence in failing to test the "shed-virus" vaccine as required by the statutes as set forth above. The Petitioners assert that the decision not to test it could not be discretionary since the decision to use the shed-virus vaccine on unsuspecting subjects, was unconstitutional.

Therefore, Petitioners ask that this Writ be granted and that the portion of the Court of Appeals holding that the shed-virus need not have been tested, be reversed, and the Petitioners cause

of action based on such allegations be allowed to proceed.

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Appendix

UNITED STATES COURT OF APPEALS

FOR THE EIGHTH CIRCUIT

No. 80-1886

Lora E. Loge and Roger S. Loge,

Plaintiffs/Appellants,

v.

United States of America and unknown employees of the Department of Health, Education, and Welfare,

Defendants/Appellees.

Appeal from the United States District Court for the Western District of Arkansas

Submitted: June 15, 1981

Filed: November 6, 1981

Before ROSS and ARNOLD, Circuit Judges; and HANSON, Senior District Judge.*

Reported at 662 F. 2d 1268 (1981)

*The Honorable William C. Hanson, Senior District Judge, Northern and Southern Districts of Iowa, sitting by designation.

HANSON, Senior District Judge.

Lora Loge contracted paralytic polio after her infant son was inoculated with a trivalent, live, oral poliovirus vaccine trade named Orimune. She and her husband sued the United States and unknown employees of the Department of Health, Education, and Welfare[1] (HEW) under the Federal Tort Claims Act[2] (FTCA) and the Constitution alleging liability based on negligent and willful acts and omissions committed in the regulating, testing, and licensing of Orimune. The government moved to dismiss the complaint for lack of subject matter jurisdiction and for failure to

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[1]This department has since been redesignated the Department of Health and Human Services. 20 U.S.C. § 3508(a).

[2]28 U.S.C. § § 1346(b), 2671 et seq.

state a claim upon which relief could be granted. F.R.Civ.P. 12(b)(1) and (6). The district court[3] dismissed the complaint "for failure to state a cause of action" (R. 83), and the Loges appeal. We affirm in part and reverse in part.

I

In testing the sufficiency of the Loges' amended complaint, the district court was constrained to accept all material allegations as true and to construe them liberally in favor of plaintiffs. Park View Heights Corp. v. City of Black Jack, et al., 467 F.2d 1208, 1212 n.3 (8th Cir. 1972). Only if "it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief" should

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[3]The Honorable Paul X Williams, Chief Judge, United States District Court for the Western District of Arkansas.

the complaint be dismissed. Conley v. Gibson, 355 U.S. 41, 45-46 (1957). The material allegations in this case indicate the following.

In June 1963, the Secretary of HEW licensed Lederle Laboratories to manufacture Orimune--a trivalent, live, oral polio-virus vaccine. See 42 U.S.C. § 262(a); 21 C.F.R. § 630.10(a). Orimune is composed of all three Sabin strains of live poliovirus corresponding to the three different types of polio (known as Types 1, 2, and 3), thus the designation "trivalent." A characteristic of live Sabin polio vaccines such as Orimune is that not only is the vaccine's recipient immunized from polio, but unimmunized persons who come into close contact with the recipient also are immunized through a shed virus which spreads from the recipient to the "contact." Because Sabin strains contain the live polio virus, there is

a risk that either a recipient or a contact could develop polio. Accordingly, the Secretary has promulgated regulations pertaining to the safety and potency of these strains which serve to protect susceptible persons from contracting the disease.[4] Drug manufacturers must prove their product's conformity to these regulations before the Secretary will issue a license to manufacture. 42 U.S.C. § 262(d).

A risk-free alternative to inoculation with the live Sabin vaccine is the Salk Vaccine in which the virus is killed so that the recipient cannot contract polio nor can the recipient shed a live virus to unimmunized contacts. But the Secretary has promoted the use of risk-bearing live vaccines because they

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[4] 21 C.F.R. § § 630.10-630.18. At the time of Lederle's licensing, these regulations were found at 42 C.F.R. § § 73.110-73.118.

are able to effect total immunization of the public through transmission of the shed virus with less than total inoculation.

Mrs. Loge was exposed to the shed virus in 1976 after a doctor inoculated her infant son Todd with Orimune. Within one month after her son's inoculation, Mrs. Loge was stricken with a vaccine-associated case of poliomyelitis, Type 2. As a result, she is now a paraplegic. The loges brought suit in the United States District Court for the Western District of Arkansas against the United States and unknown employees of the Department of HEW. The district court liberally construed their amended complaint to state the following claims against the United States under the FTCA based on the Secretary of HEW's negligence in:

> (1) licensing all spread virus vaccines including Orimune, without requiring the manufacturer to produce

the information required by 21 C.F.R. § 630.10(b)(2);

(2) licensing all live oral poliovirus vaccines without testing their safety for persons in close proximity to those inoculated, but who themselves have not received the vaccine;

(3) licensing all live oral poliomyelitis vaccines when the Secretary knew that the viruses reproduced within the inoculated person would not pass the safety requirements applicable to the viruses contained within the inoculant;

(4) licensing Types 1, 2, and 3 of the Sabin poliomyelitis live vaccine without establishing that it was free from harmful effect on individuals who had been determined to be particularly susceptible to the disease;

(5) licensing Orimune without issuing regulations designed to insure its continued safety;

(6) failing to apply the review procedures set forth in 21 C.F.R. § 601.25;

(7) failing to enact regulations which would assure the safety of trivalent oral polio vaccine as defined in 21 C.F.R. § 600.3(p);

(8) subjecting Mrs. Loge to shed virus inoculation without her knowledge or consent;

(9) failing to approve a stronger package insert warning about adverse reactions;

(10) failing to use due care in approving Lederle Lot No. 451-162--the vaccine lot from which Todd Loge received his inoculation--of the trivalent, live, oral polio vaccine.

R. 73-74.

Additionally the Loges pleaded that under Bivens v. Six Unknown Federal Narcotics Agents, 403 U.S. 388 (1973) and Carlson v. Green, 446 U.S. 14 (1980), they have a cause of action for damages directly under the Constitution for deprivation of Mrs. Loge's rights under the Fifth Amendment and her right of privacy. They claim that the government knowingly deprived Mrs. Loge of these rights in pursuing a national policy to vaccinate everyone against polio, including persons such as Mrs. Loge who did not voluntarily submit to the immunization program.

II

A. Before a cause of action against the United States can be stated, the hurdle of sovereign immunity must be overcome. This is the purpose of the FTCA.

> The Federal Tort Claims Act is not a federal remedial scheme at all, but a waiver of sovereign immunity that permits an injured claimant to recover damages against the United States where a private person "would be liable to the claimant in accordance with the law of the place where the act or omission occurred." 28 U.S.C. § 1346(b); see also 28 U.S.C. § 2674.

Carlson v. Green, supra at 28 n.1 (Powell, J. concurring). The district court construed the Loges' amended complaint to state several causes of action which failed to overcome this initial hurdle because they attacked acts or omissions by the Secretary of HEW that were "discretionary." The FTCA does not waive sovereign immunity for "[a]ny claim ... based upon the exercise or performance or the failure to

exercise or perform a discretionary function or duty on the part of a federal agency or an employee of the Government, whether or not the discretion involved be abused." 28 U.S.C. § 2680(a). Insofar as the Loges' amended complaint alleged that the government was negligent in promulgating or failing to promulgate regulations that would ensure the safety of live, oral poliovirus vaccines and properly protect susceptible persons such as Mrs. Loge, the district court correctly found that such actions by the government were discretionary functions and therefore immune from suit under FTCA. Cf. Dalehite v. United States, 346 U.S. 15, 27 (1953) ("It was not 'intended that the constitutionality of legislation, the legality of regulations, or the propriety of a discretionary administrative act, should be tested through the medium of a damage suit for tort.'").

On appeal the Loges challenge this finding in only one respect: the district court found that the regulations do not require the shed virus to be tested for safety, concluded that the Loges were essentially attacking the government for its failure to promulgate such regulations, and held that a nonactionable discretionary function was therefore implicated. The Loges claim that the regulations do require testing of the shed virus. They contend the shed virus is an "analogous product" to a virus; therefore it is within the definition of "biological products"[5] which are subject to licensing regulations. Title 21 C.F.R. § 600.3(h)(5)(i) states that a product is analogous to a virus "if prepared from or with a virus or agent

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[5]"'Biological product' means any virus, therapeutic serum, toxin, antitoxin, or analogous product applicable to the prevention, treatment, or cure of diseases or injuries of man." 21 C.F.R. § 600.3(h).

actually or potentially infectious, without regard to the degree of virulence or toxicogenicity of the specific strain used." (emphasis added). The "analogous product" obviously being referred to is a vaccine, which is prepared from a virus. Thus the live, oral polio vaccine is an analogous product to the Sabin viral strains because it is prepared from those strains. The same cannot be said for the shed virus. It is not a product analogous to a virus because it is not "prepared from or with a virus or agent;" it is itself a virus.

Nor is the shed virus, as the Loges further contend, a "recommended dosage" of a poliovirus strain. The regulations require that data must be submitted to the Commissioner of Food and Drugs "which establish that each such strain is free of harmful effect upon administration in the recommended dosage to at least 1 million people susceptible to poliomyelitis ..." 21 C.F.R. § 630.10 (b)(2). The recommended dosage to which

this regulation refers is the dosage of poliovirus strains "used in the manufacture of poliovirus vaccine." See 21 C.F.R. § 630.10(b)(2). The shed virus clearly is not a strain used in the manufacture of poliovirus vaccine. In short, the regulations are plainly designed to ensure the safety of live, oral poliovirus vaccine upon its direct recipients. No regulations require data showing the safety of the shed virus on contacts. To the extent that the Loges' amended complaint may be construed to state a claim attacking the government for this regulatory omission, the district court was correct in concluding that a discretionary function is implicated, thus immunizing the government from suit. Accordingly, we find no error in the district court's dismissal of this cause of action or any of the other causes of action to which the discretionary

function exception was applied.

B. The district court did find that two causes of action under the FTCA were not barred by the discretionary function exception: the negligent failure of the government to require the mandatory tests of 21 C.F.R. § 630.10(b)[6] when Lederle was licensed to manufacture Orimune in 1963 and the negligent failure to follow mandatory tests when Lederle's Lot 451-162 was approved. The Secretary has no discretion to disregard the mandatory regulatory commands pertaining to criteria a vaccine must meet before licensing its manufacture or releasing a particular lot of vaccine for distribution to the public. See Griffin v. United States. 500 F. 2d 1059, 1063-69 (3d Cir. 1974).

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[6] 21 C.F.R. § 630.10(b) Criteria for acceptable seed virus. (1) Strains of attenuated poliovirus Types 1, 2, and 3 used in the manufacture of the vaccine shall be identified by: (i) Historical records including origin and techniques of

Nevertheless the district court concluded that the Loges had still failed to state a claim under FTCA because no circumstances

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attenuation, (ii) antigenic properties, (iii) neurovirulence for monkeys, (iv) pathogenicity for other animals and tissue cultures of various cell types, and (v) established virus markers including rct/40,d, and other markers shown to be associated with strain virulence.

(2) Poliovirus strains shall not be used in the manufacture of Poliovirus Vaccine, Live, Oral, unless, (i) data are submitted to the Commissioner of Food and Drugs which establish that each such strain is free of harmful effect upon administration in the recommended dosage to at least 1 million people susceptible to poliomyelitis, under circumstances where adequate epidemiological surveillance of neurological illness has been maintained, and, (ii) each such strain produces a vaccine meeting the safety and potency requirements of §§ 630.11, 630.15 and 630.16(b). Susceptibility shall be demonstrated by §§ 630.11, 630.15, and 630.16(b). Susceptibility shall be demonstrated by blood tests, stool examinations and other appropriate methods.

(3) Each seed virus used in manufacture shall be demonstrated to be free of extraneous microbial agents except for unavoidable bacteriophage.

(4) No seed virus shall be used for the manufacture of poliovirus

were alleged "where the United States, if a private person, would be liable to the claimant in accordance with the law of the place where the act or omission occurred." 28 U.S.C. § 1346(b). This section has been construed to require

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vaccine unless its neurovirulence in Macaca monkeys is no greater than that of the Reference Attenuated Poliovirus distributed by the Bureau of Biologics. The neurovirulence of the seed virus shall be demonstrated by the following tests to be performed by the manufacturer: (i) The test prescribed in § 630.16 (b)(1) using seed virus as test material in place of monovalent virus pool material and (ii) the following comparative intramuscular neurovirulence test: Each of at least 10 monkeys shall be injected with a total of 5.0 ml. of the seed virus under test in one or more proximate locations of either a gluteus or gastrocnemius muscle. Similar injections shall be made in another group of 10 monkeys using the Reference Attenuated Poliovirus. Each monkey shall be injected intramuscularly with no less than 10 TCID of viral inoculum. All monkeys shall be observed for 17 to 21 days and a comparative evaluation shall be made of the evidence of neurovirulence of the virus under test and the Reference Attenuated Poliovirus, as prescribed in § 630.16(b)(1)(iii).

that the entire law of the place where the act or omission occurred must be applied, including its choice of law principles. Richards v. United States, 369 U.S. 1 (1962).

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(5) Subsequent and identical neurovirulence tests shall be performed in monkeys whenever there is evidence of a change in the neurovirulence of the production virus, upon introduction of a new production seed lot, and as often as necessary otherwise to establish to the satisfaction of the Commissioner of Food and Drugs that the seed virus strains for vaccine manufacture have maintained their neurovirulence properties as set forth in § 630.16(b)(1)(iii).

(6) The Commissioner of Food and Drugs may, from time to time, prohibit the use of a specified strain whenever he finds it is practicable to use another strain of the same type which is potentially less pathogenic for man, and that it will produce a vaccine of greater safety and of at least equivalent potency.

This regulation's precursor, 42 C.F.R. § 73.110(b), in effect when Lederle was licensed to manufacture Orimune, was virtually identical except that under subsection (2), the strain was required to be tested on 100,000 susceptible persons instead of 1 million such persons.

Without deciding which venue's law applied, the district court concluded that neither the law of the District of Columbia--the place of the negligent acts and omissions--nor the law of Arkansas--the place of the harmful impact--imposes a duty of due care on a person for activity similar to the government's in this case. We find, however, that under the applicable choice of law principles, Arkansas law applies and further that a cause of action has been stated under the law of Arkansas.

The allegations in the complaint indicate that the negligent acts and omissions by the government occurred in the District of Columbia, thus, under Richard, supra, the District's choice of law principles apply. The District of Columbia applies an interest analysis under which we must identify the state policies underlying each law in conflict and decide which state's policy would be advanced by having its law

applied to the facts at bar. Gelley v. Astra Pharmaceutical Products, Inc., 610 F.2d 558, 561 (8th Cir. 1979), quoting Semler v. Psychiatric Institute of Washington, D. C., 575 F.2d 922, 924 (D. C. Cir. 1978); see generally, G. L. Milhollin, The New Choice of Law in the District of Columbia, 24 Cath. U. L. Rev. 448 (1975). The law of the District of Columbia as construed by the Eighth Circuit in Gelley prohibits recovery by an injured party against the government under the circumstances as alleged in this case. It therefore seems that the underlying policy is to protect the government/defendant from liability for negligence in regulating drug safety. The Arkansas courts have not addressed this issue, but the district court predicted they would apply principles set out in the Restatement (Second) of Torts § 324A (1971), which governs liability to third

persons for the negligent performance of an undertaking.[7] In this case, presumably the government could be found liable under the theory that it failed to exercise reasonable care in undertaking to ensure the safety of live, oral poliovirus vaccine. The underlying policy goal of this tort rule would appear to be to compensate the injured.

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[7] § 324A. Liability to Third Person for Negligent Performance of Undertaking.

One who undertakes, gratuitously or for consideration, to render services to another which he should recognize as necessary for the protection of a third person or his things, is subject to liability to the third person for physical harm resulting from his failure to exercise reasonable care to protect his undertaking, if

(a) his failure to exercise reasonable care increases the risk of such harm, or

(b) he has undertaken to perform a duty owed by the other to the third person, or

(c) the harm is suffered because of reliance of the other or the third person upon the undertaking.

Because the policies of the tort rules of the two jurisdictions conflict, we must determine whether Arkansas's interest in the application of its rule outweighs the countervailing interest of the District of Columbia. Key factors in making this determination include the place where the injury occurred, and the residence of the parties. Gelley, supra, at 561 n.4: see Restatement (Second) of Conflict of Laws §§ 145 (1971). Since plaintiffs are residents of Arkansas and the injury occurred in this state, we find applicable the Arkansas rule in favor of protecting its citizens from injuries under such circumstances as are alleged in this case.

We also find that the district court erred in concluding that despite the prevailing rule in Arkansas, the Loges failed to allege circumstances under which relief could be granted. The

district court summarily concluded that under Restatement § 324A (supra n.7), "the government could not be said to have increased the risk which was inherent in the drug," the government undertook no duty owed by the drug manufacturer to the Loges, and Mrs. Loge could not be said to have relied on the government to ensure the vaccine met established safety and potency requirements. In making these determinations, the district court failed to give proper deference to the Loges' claims: "The question ... is whether in the light most favorable to plaintiff, and with every doubt resolved in his behalf, the complaint states any valid claim for relief." 5 C. Wright & A. Miller, Federal Practice and Procedure, § 1357 at 601 (1969) (footnotes omitted). Such deference is particularly important where, as here, the plaintiffs are first put on notice of the applicable rule

of law in the district court's Memorandum Opinion ruling on the motion to dismiss. Construing the Loges' allegations in their favor, we find that claims have been stated under any one of the three alternative grounds for liability stated in Restatement § 324A. It can be said that the government increased the risk of harm to the Loges by licensing an allegedly untested product, Orimune, and by releasing to the public an allegedly untested or negligently tested lot of that vaccine: if either the product itself or a particular lot of that product failed to conform to standards established by the regulations, then proper testing or proof of testing would have revealed the nonconformity and the vaccine would never have been disseminated to Todd Loge. Likewise, it can be said that the government undertood a duty owed by the drug manufacturer to the Loges

when it required that proof of the drug's safety be demonstrated to the government before releasing it to the public. Finally, the Loges alleged they relied on the government's use of due care in approving for release the particular vaccine lot that was eventually administered to Todd Loge. Therefore, the district court erred in concluding that the Loges had failed to state a claim under the law of Arkansas.

III

We turn now to the Loges' claims said to arise under the Constitution of the United States. The Loges seek redress under the authority of Bivens v. Six unknown Federal Narcotics Agents, 8

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[8] Bivens established that the victims of a constitutional violation by a federal agent have a right to recover damages against the official in federal court despite the absence of any statute conferring such a right. Recently the Supreme Court held that a Bivens action is available even though plaintiff's

supra, from various unknown government agents and employees. They alleged that through their policy decisions to promote the use of live, oral poliovirus vaccine over killed virus vaccine, government officials intentionally and recklessly sacrificed Mrs. Loge's good health for the benefit of the health and welfare of the public, constituting: (a) an uncompensated taking of her private property ("to wit, Mrs. Loge's body") for public use; (b) a deprivation of her life, liberty and property without due process of law; and (c) an invasion of her right of privacy. The district court held that these allegations failed to state a cause of action because "[t]he Constitution does not include a guarantee to be free from personal injury under the circumstances of this case."

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allegations could also support a suit filed under the FTCA. Carlson v. Green, 446 U.S. 14 (1980).

Not even the most general clauses of the Constitution, such as the Due Process Clause of the Fifth Amendment, should be read as conferring upon the courts the right to superintend every action of government that may adversely affect some citizen. While we recognize our duty to condemn forthrightly any governmental action that contravenes the Constitution, we are also aware that this function must be kept within bounds. To find that the Loges' allegations state causes of action under the Constitution would be to overstep these bounds. We therefore affirm the district court's dismissal of these constitutional claims.

Accordingly, we affirm the district court's order of dismissal in all respects except for the dismissal of the Loges' two claims under the FTCA alleging the government's violation of its own regulations. As to these claims, we reverse

and remand for further proceedings consistent with this opinion.

A true copy.

Attest:

CLERK, U. S. COURT OF APPEALS,
EIGHTH CIRCUIT.

IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF ARKANSAS

FAYETTEVILLE DIVISION

LORA E. LOGE and
ROGER S. LOGE,
HER HUSBAND PLAINTIFFS

V.

UNITED STATES OF AMERICA DEFENDANT

FILED JULY 28, 1980
Civil No. 79-5088

Reported At 494 F.Supp. 883 (1980)

MEMORANDUM OPINION

In this case, plaintiffs, Mr. and Mrs. Roger Loge, seek damages under the Federal Tort Claim Act, 28 U.S.C. §§ 2671 et seq. The case is before the Court on the defendant's motion to dismiss.

The plaintiffs contend that all live virus poliomyelitis vaccines reproduce within the inoculated person and can

spread to others who are in close contact with the one inoculated; that Mr. and Mrs. Loge decided to have their infant son inoculated with a live polio vaccine, but that Mrs. Loge chose not to subject herself to the risk involved in being vaccinated; that after the infant received a trivalent live poliomyelitis vaccine on July 26, 1976, manufactured under the tradename "orimune," Mrs. Lora Loge contracted polio which rendered her permanently paralyzed; and that Mrs. Loge's poliomyelitis was caused by the inoculation given to her child.

In their complaint as amended, the Loges contend the United States is liable because the Secretary of Health, Education and Welfare was negligent in the following respects:

(1) licensing all spread virus vaccinations, including Orimune, without requiring the manufacturer to

produce the information required by 21 C.F.R. § 630.10(b)(2);

(2) licensing all live oral poliovirus vaccines without testing their safety for persons in close proximity to those inoculated, but who themselves have not received the vaccine;

(3) licensing all live oral poliomyelitis vaccines when it knew the viruses reproduced within the inoculated person would not pass the safety requirements applicable to the viruses contained within the inoculant;

(4) licensing Types I, II and III of the Sabin poliomyelitis live vaccine without establishing that it was free from harmful effect on individuals who had been determined to be particularly susceptible to the disease;

(5) licensing Orimune without issuing regulations designed to insure its continued safety;

(6) failing to apply the review procedures set forth in 21 C.F.R. § 601.25;

(7) failing to enact regulations which would assure the safety of trivalent oral polio vaccine as defined in 21 C.F.R. § 600.3(p);

(8) subjecting Mrs. Loge to "shed-virus" inoculation without her knowledge or consent;

(9) failing to approve a stronger package insert warning about adverse reactions;

(10) failing to use due care in approving Lederle Lot Number 451-162 of the trivalent oral polio vaccine.

The plaintiffs also pleaded that the defendant had subjected Mrs. Loge to exposure to the vaccine without her consent

in violation of her right to privacy and security guaranteed by the Fourth Amendment to the United States Constitution and had deprived her of life, liberty and property in violation of the Fifth Amendment. The plaintiffs pleaded that the constitutional deprivations were knowingly committed by the government in furtherance of the national policy to vaccinate everyone, including those such as plaintiff who do not voluntarily submit to the immunization program. The plaintiffs contend that non-shed-virus vaccines are available.

The constitutional claim is discussed at the end of this opinion, after discussion of the claim under the Federal Tort Claims Act.

In its motion to dismiss, the government contends that the plaintiffs have failed to state a cause of action.

The first issue raised by the government is that the Federal Tort Claims Act imposes

liability on the government for acts which would be actionable if performed by individuals; and that since the granting or denial of a license is a particularly governmental function which can never be the basis of liability on the part of an individual, the government cannot be held liable under the Federal Tort Claims Act.

The United States Supreme Court has rejected the governmental function test, holding that the government is liable, if a private person would be liable, under like circumstances. Indian Towing Co. v. United States, 350 U.S. 61 (1955).

The second issue raised by the government is that plaintiffs' cause of action falls within 28 U.S.C. §§ 2680(a), which provides as follows:

> The provisions of this chapter and section 1346(b) of this title shall not apply to---
>
> (a) Any claim based upon an act or omission of an employee of the Government,

> exercising due care, in the execution of a statute or regulation, whether or not such statute or regulation be valid, or based upon the exercise or performance or the failure to exercise or perform a discretionary function or duty on the part of a federal agency or an employee of the Government, whether or not the discretion involved be abused.

The second clause of this section reserves immunity for the government for the exercise or omission of discretionary functions regardless of due care.

In plaintiffs' complaint as amended, they contend the government is liable for promulgation of certain regulations in that the regulations failed to properly protect persons such as Mrs. Loge. In other allegations, plaintiffs contend that the government licensed the vaccine, without requiring the certain tests designed to measure its effect on those who never directly received the vaccine, but were recipients of the shed-viruses. The

regulations did not and do not require such tests. Plaintiffs are therefore attacking the government for its failure to promulgate such regulations.

In other sections of their complaint, plaintiffs contend the government should not have licensed the live shed-virus vaccines without establishing its safety on non-recipients. There is no regulation mandating such tests and, therefore, plaintiffs are contending the government is liable for failure to promulgate a certain regulation.

The promulgation of a regulation is a discretionary function. As stated by the Court in Dalehite v. United States, 346 U.S. 15, 25 (1953):

> [It] was not 'intended that the constitutionality of legislation, the legality of regulations, or the propriety of a discretionary administrative act should be tested through the medium of a damage suit for tort.'

We also hold that the government's decision to subject persons such as Mrs. Loge to inoculation by the shed-viruses, as distinguished from non-shed-virus vaccines, was a policy decision and cannot give rise to liability under the Federal Tort Claims Act.

> It is unnecessary to define, apart from this case, precisely where the discretion ends. It is enough to hold, as we do, that the 'discretionary function or duty' that cannot form a basis for suit under the Tort Claims Act includes more than the initiation of programs and activities. It also includes determinations made by executives or administrators in establishing plans, specifications or schedules of operations. Where there is room for policy judgment and decisions, there is discretion. [Emphasis added]

Dalehite v. United States, 346 U.S. 15, 35-36 (1953).

The same principle protects the government for its decision concerning the warning on the package insert. The government contends that the discretionary

function clause of section 2680(a) bars not just attacks on the regulations themselves, but also attacks on the issuance of every license or permit. We disagree. The regulations often establish mandatory criteria for the issuance or denial of a license or permit. In such a situation, the licensor lacks the discretion to waive the requirements. His actions, with respect to the issuance or denial of the license, are not discretionary within the meaning of 28 U.S.C. §§ 2680(a). Griffin v. United States, 500 F.2d 1059, 1068-1069 (3rd Cir. 1974).

In plaintiffs' complaint, they contend the government is liable for licensing all live virus vaccines, including Orimune, without requiring that data be produced showing the vaccine meets certain criteria. 21 C.F.R. §§ 630.10(b)(1980) is identical to the regulation in effect before 1976 which was codified as 42 C.F.R. §§ 73.114.

The regulation provides as follows:

(b) Criteria for acceptable strains and acceptable seed virus. (1) Strains of attenuated poliovirus Types 1, 2, and 3 used in the manufacture of the vaccine shall be identified by: (i) Historical records including origin and techniques of attenuation, (ii) antigenic properties, (iii) neurovirulence for monkeys, (iv) pathogenicity for other animals and tissue cultures of various cell types, and (v) established virus markers including rct/40,d, and other markers shown to be associated with strain virulence.

(2) Poliovirus strains shall not be used in the manufacture of Poliovirus Vaccine, Live, Oral, unless (i) data are submitted to the Commissioner of Food and Drugs which establish that each such strain is free of harmful effect upon administration in the recommended dosage to at least 1 million people susceptible to poliomyelitis, under circumstances where adequate epidemiological surveillance of neurological illness has been maintained, and, (ii) each such strain produces a vaccine meeting the safety and potency requirements of §§ 630.11, 630.15 and 630.16(b). Susceptibility shall be demonstrated by §§ 630.11, 630.15, and 630.16(b).

Susceptibility shall be demonstrated by blood tests, stool examinations and other appropriate methods.

(3) Each seed virus used in manufacture shall be demonstrated to be free of extraneous microbial agents except for unavoidable bacteriophage.

(4) No seed virus shall be used for the manufacture of poliovirus vaccine unless its neurovirulence in Macaca monkeys is no greater than that of the Reference Attenuated Poliovirus distributed by the Bureau of Biologics. The neurovirulence of the seed virus shall be demonstrated by the following tests to be performed by the manufacturer: (i) The test prescribed in § 630.16(b)(1) using seed virus as test material in place of monovalent virus pool material and (ii) the following comparative intramuscular neurovirulence test: Each of at least 10 monkeys shall be injected with a total of 5.0 ml. of the seed virus under test in one or more proximate locations of either a gluteus or gastrocnemius muscle. Similar injections shall be made in another group of 10 monkeys using the Reference Attenuated Poliovirus. Each monkey shall be injected intramuscularly with no less than 10 TCID of viral inoculum.

> All monkeys shall be ovserved for 17 to 21 days and a comparative evaluation shall be made of the evidence of neurovirulence of the virus under test and the Reference Attenuated Poliovirus, as prescribed in § 630.16(b)(1)(iii).
>
> (5) Subsequent and identical neurovirulence tests shall be performed in monkeys whenever there is evidence of a change in the neurovirulence of the production virus, upon introduction of a new production seed lot, and as often as necessary otherwise to establish to the satisfaction of the Commissioner of Food and Drugs that the seed virus strains for vaccine manufacture have maintained their neurovirulence properties as set forth in § 630.16(b)(1)(iii).
>
> (6) The Commissioner of Food and Drugs may, from time to time, prohibit the use of a specified strain whenever he finds it is practicable to use another strain of the same type which is potentially less pathogenic for man, and that it will produce a vaccine of greater safety and of at least equivalent potency.

We hold that this regulation is mandatory. It does not vest the licensor with discretion concerning whether it can waive

test results establishing the vaccine's effect on one million susceptible persons. To the extent that plaintiffs contend Orimune was licensed without complying with this regulation, we cannot say that plaintiffs' complaint is barred by the discretionary function exception to the Federal Tort Claims Act.

Plaintiffs also contend that defendant is liable for licensing all Sabin strains without requiring the mandatory test data of 21 C.F.R. § 630.10(b). The Sabin strains were licensed before promulgation of the regulations and their licensing in such a situation was discretionary. Griffin v. United States, 351 F.Supp. 10, 26 n. 20 (E.D. Pa. 1972) rev'd on other grounds, 500 F.2d 1059 (3rd Cir. 1974).

The plaintiffs have also pleaded that the government is liable for failing to follow the review procedures set out in 21 C.F.R. § 601.25, which provides,

in part, as follows:

> (a) Advisory review panels. The Commissioner of Food and Drugs shall appoint advisory review panels (1) to evaluate the safety and effectiveness of biological products for which a license has been issued pursuant to section 351 of the Public Health Service Act, (2) to review the labeling of such biological products, and (3) to advise him on which of the biological products under review are safe, effective, and not misbranded. An advisory review panel shall be established for each designated category of biological product. The members of a panel shall be qualified experts, appointed by the Commissioner, and shall include persons from lists submitted by organizations representing professional, consumer and industry interests. Such persons shall represent a wide divergence of responsible medical and scientific opinion. The Commissioner shall designate the chairman of each panel, and summary minutes of all meetings shall be made.

The Court takes judicial notice that the advisory review panel has not yet issued its report. The vaccine which Mrs. Loge's son received was ditributed pursuant to Lederle's original license issued in 1963.

Any omissions in mandatory tests in conjunction with the review cannot have affected Mrs. Loge.

Plaintiffs have pleaded that the government failed to use due care in approving Lot 451-162. Since the promulgating or omission of regulations is discretionary, but adherence to them is not, we infer that plaintiffs are pleading the government failed to follow one of its mandatory, nondiscretionary regulations in approving Lot 451-162. To this extent, we cannot say that plaintiffs' claim is barred by the discretionary function exemption of 28 U.S.C. §§ 2680.

In its motion to dismiss, the government contends that plaintiffs' complaint fails to state a cause of action because the government owes no duty, sine qua non of negligence, concerning the issuance of licenses. We have held that the discretionary function exemption of

28 U.S.C. § 2680(a) bars each ground for relief asserted by plaintiffs under the Federal Tort Claims Act, except for two: failure to require the mandatory tests of 21 C.F.R. § 630.10(b) when Orimune was licensed in 1963; and failure to follow mandatory tests when Lederle's Lot 451-162 was approved. We now hold that these two remaining allegations of negligence fail to state a cause of action because under Arkansas law and the law of Washington, D. C., there is no duty to use due care imposed on one in a similar situation.

In Gelley v. Astra Pharmaceutical Products, Inc., 610 F.2d 558 (8th Cir. 1978), the plaintiff asserted liability on the part of the government for negligently failing to withdraw xylocaine from interstate commerce. The Court noted that under the law of the District of Columbia, no cause of action exists against an individual for similar activity.

The Court also noted that under Minnesota law, the place of the harmful impact, no cause of action exists. In the District of Columbia, there is no tort duty imposed on private persons to perform activities analogous to the granting or denial of licenses for drugs and in the absence of such duty, there can be no liability for negligence on the part of an individual or the government. Gelley v. Astra Pharmaceutical Products, Inc., 466 F.Supp. 182 (D. Minn. 1979) aff'd on other grounds, 610 F.2d (8th Cir. 1979).

Under Arkansas law, all political subdivisions of the state are immune from tort liability and therefore there are no Arkansas cases dealing with tort liability for regulatory acts and omissions. This does not of itself defeat a cause of action under the Federal Tort Claims Act. Rayonier Inc. v. United States, 352 U.S. 315 (1957). There also are no

Arkansas cases which address the issue of duty owed by one to another who gratuitously undertakes services for a third party, but we hold that if the courts of Arkansas were faced with the issue they would follow the principles set out in the Restatement (Second) of Torts § 324 A which provides as follows:

> § 324 A. Liability to Third Person for Negligent Performance of Undertaking
>
> One who undertakes, gratuitously or for consideration, to render services to another which he should recognize as necessary for the protection of a third person or his things, is subject to liability to the third person for physical harm resulting from his failure to exercise reasonable care to protect his undertaking, if
>
> (a) his failure to exercise reasonable care increases the risk of such harm, or
>
> (b) he has undertaken to perform a duty owed by the other to the third person, or
>
> (c) the harm is suffered because of reliance of the other or the third person upon the undertaking.

Applying these principles to the case at bar, we hold that by licensing the trivalent polio oral vaccine the government gratuitously undertoo services to the drug manufacturer which it should recognize as necessary for the protection of the residents of the United States. As such, the government would be liable if it were a private individual under Arkansas law if the government's failure to exercise reasonable care increased the risk, if the government undertook to perform a duty owed by the drug manufacturers to the recipients of the vaccines, or if the harm suffered by Mrs. Loge was because of reliance on the government.

In licensing the trivalent vaccine, the government cannot be said to have increased the risk which was inherent in the drug. Neither can we say that the government undertook the duty owed by the drug manufacturer to those who would

be affected by the vaccine.

We also find that the harm suffered by Mrs. Loge cannot be said to have been caused by reliance on the government.

We therefore hold that the Loges' complaint fails to state a cause of action.

The plaintiffs also contend that their constitutional rights to privacy, to due process, of law and to just compensation have been abridged by the defendants, United States and unknown employees of the Department of Health, Education and Welfare.

We recognize that federal employees and agents may be liable for their unconstitutional acts. Bivens v. Six Unknown Fed. Narcotics Agents, 403 U.S. 388 (1971). We also recognize that the Federal Tort Claims Act does not bar an action for deprivation of constitutional rights. Carlson v. Green, ____ U.S. ____, 48 Law W. 4425 (1980). We hold, however, that

plaintiffs have not stated a cause of action for deprivation of constitutional rights. The Constitution does not include a guarantee to be free from personal injury under the circumstances of this case.

The Clerk will prepare an order in accord with this opinion which dismisses the action for failure to state a cause of action.

This 28th day of July, 1980.

Signed: Paul X Williams
United States District Judge

IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF ARKANSAS
FAYETTEVILLE DIVISION

NO. 79-5088

LORA E. LOGE, &
ROGER S. LOGE,
her husband PLAINTIFFS,

V.

UNITED STATES OF AMERICA &
Unknown employees of the
DEPARTMENT OF HEALTH, EDUCATION
AND WELFARE, (H.E.W.) DEFENDANTS.

AMENDED COMPLAINT

COME NOW THE PLAINTIFFS, LORA E. LOGE AND ROGER S. LOGE, her husband, by and through their undersigned attorney, and amend their Complaint under the FEDERAL TORT CLAIMS ACT, and for cause of action show unto this Court as follows:

1) This action is brought pursuant to the Courts jurisdiction under the Federal Tort Claims Act, 28 USC Section 2671, and pursuant to the Courts jurisdiction under 28 USC Section 1331.

2) This action is for an amount in

excess of $10,000.00.

3) That Plaintiffs are residents of the City of Fayetteville in Washington County, Arkansas, within the Western District of Arkansas, Fayetteville Division.

4) That this claim has been timely presented to the appropriate Federal Agency, the Department of Health, Education and Welfare, on July 20, 1978, and that said claim was denied on July 7, 1979.

5) This Amended Complaint is merely a restatement of the Complaint filed on Nov. 29, 1979 with the addition of an allegation of the Courts jurisdiction under 28 USC Section 1331 and the addition of unknown Defendants. This restatement is intended to clarify the issues made in the original Complaint as challenged in Defendant's Motion to Dismiss.

6) The unknown Defendants listed in this Amended Complaint are the Doctors, agents, and employees of the Defendant,

United States of America, who were responsible for the decision to sacrifice a number of people each year through Defendants' live, oral, poliovirus vaccine program and who were responsible for the decision to cause unknowing and involuntary persons, including the Plaintiff wife, to be immunized with the untested and potentially lethal "shed-virus" vaccine.

7) In July, 1976, and at all times pertinent herein, Lederle Laboratories, a wholly owned division of American Cyanamid, Inc., a Maine corporation, was a manufacturer of pharmaceutical products including biological products such as vaccines within the meaning of 42 U.S.C. Section 262, as amended.

8) Lederle did apply for and receive a license to manufacture and distribute live poliomyelitis vaccines for TYPES I, II, & II poliomyelitis, which vaccines were made from live polio viruses known

as the Sabin strains. Furthermore, the license to manufacture and distribute such vaccine strains was issued in 1960 or 1961, the exact date of which is within the knowledge of the Defendant.

9) In June, 1963, Lederle did apply for and receive a license to market, manufacture and distribute a vaccine composed of all three Sabin strains of live polioviruses. This vaccine is known as ORIMUNE and is a Trivalent, Live, Oral, Poliovirus Vaccine.

10) That from and after the aforementioned dates, Lederle has marketed and distributed ORIMUNE to hospitals, clinics, health departments and private physicians, including Dr. Wade Burnside, M.D., of Fayetteville, Arkansas.

11) Defendant tested and released for distribution the Lederle vaccine, Lot Number 451-162, and that lot was then distributed, in part to Dr. Wade Burnside.

12) According to Defendants' records, a dosage of that lot number was administered to Todd Loge, the son of Lora E. Loge and Roger S. Loge, on July 26, 1976.

13) Lora E. Loge was taking care of her infant son, Todd, at all times before and after the administration of the vaccine to him on July 26, 1976, and such care included kissing him as a sign of her love, breast feeding him and changing his diapers.

14) On or about August 21, 1976, Plaintiff wife, Lora E. Loge, was stricken by a severe and paralytic illness which has rendered her a permanent paraplegic and confined her to a wheel chair.

15) The Defendant has classified this paralytic illness as a vaccine associated case of poliomyelitis, TYPE II, and furthermore, that such poliomyelitis was a vaccine associated case which had been acquired through Plaintiff wife's personal contact

with a recipient of the live, oral, poliovirus vaccine.

That the Defendant, UNITED STATES OF AMERICA, DEPARTMENT OF HEALTH, EDUCATION AND WELFARE, was guilty of negligence in the following respects:

I

1) The Defendant has maintained complete and absolute control over the manufacture, distribution, licensing and release of each batch of live, oral poliovirus vaccine that is made in the United States, including the vaccine from Lederle Lot Number 451-162.

2) Defendant has licensed live, oral poliovirus vaccine strains with full knowledge that such strains result in the shedding of live polio viruses from the recipients of the vaccine and that such shed polio viruses spread to and infect persons who come into close personal contact with the recipient of the vaccine.

3) Defendant has licensed live, oral, poliovirus vaccine strains for manufacture and distribution in the United States with the intent, understanding and desire that such strains would be shed by the recipients of the vaccine, would spread to and infect unimmunized persons in close contact with the recipient of the vaccine and that such infection would thereby "vaccinate" such unimmunized persons by means of a "shed-virus" vaccine.

4) Plaintiff wife had never voluntarily participated in Defendants' polio immunization program and had not been immunized against polio prior to her contact with a "shed-virus" vaccine in July of 1976.

5) By virtue of its control, licensing and promotion of live, oral, poliovirus vaccine, Defendant intended to cause and in fact caused Plaintiff wife to be subjected to a "shed-virus" vaccination without her knowledge, consent or volition and

against her free will.

6) Defendant has not required tests showing the safety or efficacy of either the "shed-virus" vaccine or the Sabin strains used in the manufacture of the live, oral, poliovirus vaccine, under clinical trials, pertinent regulations, statutes and Congressional mandates that were applicable at the time of the licensure of the original monovalent and trivalent vaccines or that have gone into effect since such licensure.

7) Plaintiffs are members of the class of people Congress intended to protect by regulations, restrictions, statutes and mandates regarding the safety of live, poliovirus vaccines. Such statutes and regulations include 42 USC Section 262, former 42 CFR Section 73, and 21 CFR Section 600.

8) Plaintiffs have suffered injuries of the type that said statutes were

intended to prevent.

9) Defendants' failure to follow such mandatory statutes and regulations was the proximate cause of Plaintiffs' injuries.

II

1) No batch of live, oral, poliovirus vaccine may be distributed in this country without Defendants' approval.

2) Defendant performed safety tests upon and authorized the release and distribution of the vaccine used in Lederle Lot #451-162.

3) Defendant completely controls the wording about adverse reactions to live, poliovirus vaccines where such wording appears on ORIMUNE package inserts, in that:

a. Defendant provides information to the manufacturer of the vaccine so that the manufacturer can re-write such warnings.

b. No warning may be changed on the package inserts without Defendant's direct and prior approval.

4) Defendant has assumed the role of providing information about the adverse reactions of the live, oral, poliovirus vaccines to the public in general and the Plaintiff in particular.

5) Prior to 1976, Lederle Laboratories proposed a stronger warning about adverse reactions which adult contacts might have with the vaccine, but Defendant was negligent in that it failed to approve such a warning within a reasonable time.

6) Defendant intended for Plaintiffs to rely upon, and Plaintiffs did rely upon, the Defendant's approval of such warnings and upon Defendant's approval of said lot of ORIMUNE.

7) Defendant failed to exercise due care in its approval of said warnings and failed to use due care in its approval

of said lot of vaccine.

8) Defendants' failure to exercise due care was the direct and proximate cause of the Plaintiffs' injuries and damages.

III

1) Plaintiffs incorporate all of the foregoing allegations made herein and further allege that Defendants, United States of America, and its unknown officers and agents, violated the Constitutional rights of the Plaintiffs in the following respects:

2) Defendants' records indicate that a certain number of people each year since 1960 have succumbed to paralysis or death as a result of the live, oral, poliovirus vaccine strains and, furthermore, such records show that Plaintiff wife, Lora Loge, was one of the people paralyzed as a result of said live, oral, poliovirus vaccine strains in the year of 1976.

3) An absolutely safe alternative to the live, oral poliovirus vaccine strains has always existed, but that safe alternative has not been promoted by Defendants because vaccination with it does not spread a "shed-virus" vaccination to persons who come into contact with the recipient of that safe alternative.

4) While exerting complete and absolute control over poliovirus vaccination programs in the United States, the Defendants have intentionally and knowingly chosen to sacrifice the lives and limbs of a certain number of people per year with the live, oral, poliovirus vaccine in order to vaccinate persons, such as Plaintiff wife, who do not voluntarily submit to Defendants' polio immunization program.

5) The Defendants have continued this program which intentionally causes human suffering and sacrifice under the guise that the program is necessary for

the benefit of the public's health and welfare in general.

6) Plaintiff wife was one of the people sacrificed to benefit the health and welfare of the public under Defendants' polio immunization program.

7) Plaintiffs did not consent to such a sacrifice and that sacrifice included the loss of use of Plaintiff wife's legs for the remainder of her life. Furthermore, Plaintiff wife never consented to become vaccinated with the "shed-virus" vaccine which is an integral part of Defendants' polio immunization program.

8) The Defendants' intentional and reckless sacrifice of the Plaintiff wife's good health for the benefit of the health and welfare of the public constitutes:

a. a taking of her private property for public use, and

b. a deprivation of her life, liberty and property without due process

of law, and

c. an invasion of her right to privacy and security, in violation of Plaintiff's rights as guaranteed by the Constitutions of the United States and of the State of Arkansas.

9) Plaintiffs are members of the class of people that said Constitutions were intended to protect and Plaintiffs have suffered injuries of the type that said Constitutions were intended to prevent.

10) Defendants' intentional and reckless sacrifice of Plaintiff wife's good health under the guise of national health policy was arbitrary, capricious and unnecessary.

11) Defendants have intentionally and recklessly violated the Constitutional rights of the Plaintiffs, and such violation of Plaintiffs' Constitutional rights is the proximate cause of their injuries.

IV

Plaintiffs incorporate each of the

foregoing allegations and further allege that:

1) For at least six years prior to July, 1979, the major causes of paralytic poliomyelitis in the United States were the live, oral, poliovirus vaccine strains which Defendant licensed and promoted and controlled.

2) Plaintiff had decided not to be immunized with the live, oral, poliovirus vaccine strains which Defendants promoted and controlled and licensed for manufacture in the United States. Her decision not to voluntarily participate in Defendants' polio immunization program was the only logical decision in light of the afore-stated fact.

3) No State or Federal statute existed which required the Plaintiff wife to participate in Defendants' live, polio-virus, vaccine program.

4) Defendants intended to cause,

and in fact caused, Plaintiff wife's exposure to and innoculation with the "shed-virus" vaccine in accordance with its polio immunization program.

5) Plaintiff wife did not consent to innoculation with the "shed-virus" vaccine and her involuntary innoculation, intentionally caused by the Defendants, has resulted in grievous injuries and permanent damages to the Plaintiffs.

V

As a direct and proximate result of both the negligent and the intentional acts of the Defendants, Plaintiff, Lora Loage, has suffered the following elements of damage:

1) She is permanently and totally disabled.

2) She has undergone excruciating pain and suffering in the past and will continue to undergo such pain and suffering in the future.

3) She has sustained a complete loss of earnings and earning capacity.

4) Her infirmities are visible.

VI

The Plaintiff, Roger S. Loge, has sustained the following elements of damage:

1. He has incurred large medical expenses on behalf of his wife and will continue to incur such expenses in the future.
2. He has lost the services, society and consortium of his wife.
3. As a result of his wife's condition, he has found it necessary to employ help in his home.

As a result of the elements of damage set forth above, Lora E. Loge has been damaged in the sum of $1,500,000 and the Plaintiff Roger S. Loge has been damaged in the sum of $500,000.

WHEREFORE, Plaintiffs pray damages against the Defendant in the sum total of $2,000,000, for their costs and all other relief to which they may be entitled.

Walter S. Kyle
Attorney for Plaintiffs
P. O. Box 350305
Ft. Lauderdale, Florida
33335

Suite 1950
Union National Plaza
Little Rock, Arkansas
72201

IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF ARKANSAS
FAYETTEVILLE DIVISION

LORA E. LOGE, &
ROGER S. LOGE,
her husband,

PLAINTIFFS,

V.

UNITED STATES OF AMERICA, &
unknown employees of the
Department of Health, Education
and Welfare,

DEFENDANTS.

CASE NO.: 79-5088

ISSUES ON APPEAL

Plaintiffs hereby certify, by and through their undersigned counsel, that a transcript of the underlying proceedings is not required for the record on appeal and that the following is a list of the issues to be raised on appeal:

1) Whether or not the District Court was correct in holding that the facts of this case do not support a claim for violation of Plaintiffs' Constitutional rights wherein jurisdiction would lie under 28 USC §§ 1331.

2) Whether or not the District Court was correct in dismissing Plaintiffs' Complaint and Amended Complaint without giving the Plaintiffs the opportunity to prove at trial that under the allegations contained in said pleadings that;

a. The Defendant, United States of America, undertook a duty owed by the drug manufacturer to those people who would be affected by the vaccine, OR,

b. The Defendant, United States of America, increased the risk which was inherent in the drug.

3) Whether or not the District Court was correct in holding that the Defendants' decision to cause the involuntary

inoculation of Plaintiff wife with a potentially lethal viral agent without Plaintiff wife's knowledge or consent and against her free will was discretionary under the Federal Tort Claims Act and Constitutional under the provisions of the Constitution of the United States of America.

(4) Whether or not the District Court was correct in finding that the allegations of negligence contained in the Complaint and Amended Complaint failed to state a cause of action under the laws of Arkansas or the District of Columbia.

WALTER S. KYLE
ATTORNEY FOR PLAINTIFFS
P. O. BOX 350305
FT. LAUDERDALE
FLORIDA 33335
(305) 587-5953

CONSTITUTIONAL PROVISIONS, STATUTES AND REGULATIONS INVOLVED

The First Amendment to the United States Constitution provides:

> Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the Government for a redress of grievances.

The Fourth Amendment to the United States Constitution provides:

> The right of people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures, shall not be violated, and no Warrants shall issue, but upon probable cause, supported by Oath or affirmation, and particularly describing the place to be searched, and the persons or things to be seized.

The Fifth Amendment to the United States Constitution provides:

> No person shall be held to answer for a capital, or otherwise infamous crime, unless on a presentment or

indictment of a Grand Jury, except in cases arising in the land or naval forces, or in the Militia, when in actual service in time of War or public danger; nor shall any person be subject for the same offence to be twice put in jeopardy of life or limb; nor shall be compelled in any criminal case to be a witness against himself, nor be deprived of life, liberty, or property, without due process of law; nor shall private property be taken for public use, without just compensation.

The Ninth Amendment to the United States Constitution provides:

> The enumeration in the Constitution, of certain rights, shall not be construed to deny or disparage others retained by the people.

The Federal Tort Claims Act, 28 U.S.C. § 1346(b) provides:

> (b) Subject to the provisions of chapter 171 of this title, the district courts, together with the United States District Court for the District of the Canal Zone, and the District Court of the Virgin Islands, shall have exclusive jurisdiction of

> civil actions on claims against the United States, for money damages, accruing on and after January 1, 1945, for injury or loss of property, or personal injury or death caused by the negligent or wrongful act or omission of any employee of the Government while acting within the scope of his office or employment, under circumstances where the United States, if a private person, would be liable to the claimant in accordance with the law of the place where the act or omission ocurred.

The Federal Tort Claims Act, 28 U.S.C. § 2680(a) provides:

> The provisions of this chapter and section 1346(b) of this title shall not apply to--
>
> (a) Any claim based upon an act or omission of an employee of the Government, exercising due care, in the execution of a statute or regulation, whether or not such statute or regulation be valid, or based upon the exercise or performance or the failure to exercise or perform a discretionary function or duty on the part of a federal agency or an employee of the Government, whether or not the discretion involved be abused.

The Public Health Service Act, 42 U.S.C. § 262, provides in pertinent part:

> (a) No person shall sell, barter, or exchange, or offer for sale, barter, or exchange in the District of Columbia, or send, carry, or bring for sale, barter, or exchange from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession, any virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or its derivatives (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of diseases or injuries of man, unless (1) such virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product has been propagated or manufactured and prepared at an establishment holding an unsuspended and unrevoked license, issued by the Secretary as hereinafter authorized, to propagate or manufacture, and prepare such virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product for sale in the District of Columbia, or

for sending, bringing, or carrying from place to place aforesaid; and (2) each package of such virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product is plainly marked with the proper name of the article contained therein, the name, address, and license number of the manufacturer, and the date beyond which the contents cannot be expected beyond reasonable doubt to yield their specific results. The suspension or revocation of any license shall not prevent the sale, barter, or exchange of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid which has been sold and delivered by the licensee prior to such suspension or revocation, unless the owner or custodian of such virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid has been notified by the Secretary not to sell, barter, or exchange the same.

* * * *

(d) Licenses for the maintenance of establishments for the propagation or manufacture and preparation of products described in subsection (a) of this section may be issued only

> upon a showing that the establishment and the products for which a license is desired meet standards, designed to insure the continued safety, purity, and potency of such products, prescribed in regulations, and licenses for new products may be issued only upon a showing that they meet such standards. All such licenses shall be issued, suspended, and revoked as prescribed by regulations and all licenses issued for the maintenance of establishments for the propagation or manufacture and preparation, in any foreign country, of any such products for sale, barter, or exchange in any State or possession shall be issued upon condition that the licenses will permit the inspection of their establishments in accordance with subsection (c) of this section.

The pertinent portion of the regulation regarding licensure, which was promulgated pursuant to the Public Health Service Act, 42 U.S.C. § 262, and effective at the time Lederle was licensed, 42 C.F.R. 73.110(b)(2)(1961), provides:

(b) Criteria for acceptable strains and acceptable seed virus.

* * *

(2) Poliovirus strains shall not be used in the manufacture of Poliovirus Vaccine, Live, Oral, unless, (i) data are submitted to the Surgeon General which establish that each such strain is free of harmful effect upon administration in the recommended dosage to at least 100,000 people susceptible to poliomyelitis, under circumstances where adequate epidemiological surveillance of neurological illness has been maintained, and, (ii) each such strain produces a vaccine meeting the safety and potency requirements of §§ 73.114(b), 73.115, and 73.117. Susceptibility shall be demonstrated by blood tests, stool examinations and other appropriate methods.

21 C.F.R. PART 600

BIOLOGICAL PRODUCTS: GENERAL

Section 600.3 Definitions.

As used in this subchapter:

(g) "Products" includes biological products and trivalent organic arsenicals.

(h) "Biological product" means any virus, therapeutic serum, toxin, antitoxin, or analogous product applicable to the prevention, treatment or cure of diseases or injuries of man:

(1) A virus is interpreted to be a product containing the minute living cause of an infectious disease and includes but is not limited to filterable viruses, bacteria, rickettsia, fungi, and protozoa.

(5) A product is analogous:

(i) To a virus if prepared from or with a virus or agent actually or potentially infectious, without regard to the degree of virulence or toxicogenicity of the specific strain used.

(j) A product is deemed "applicable to the prevention, treatment, or cure of diseases or injuries of man" irrespective of the mode of administration or application recommended, including use when

intended through administration or application to a person as an aid in diagnosis, or in evaluating the degree of susceptibility or immunity possessed by a person, and including also any other use for purposes of diagnosis if the diagnostic substance so used is prepared from or with the aid of a biological product.

(p) The word "safety" means the relative freedom from harmful effect to persons affected, directly or indirectly, by a product when prudently administered, taking into consideration the character of the product in relation to the condition of the recipient at the time.

28 U.S.C. §§ 1254. Courts of appeals; certiorari; appeal; certified questions

Cases in the courts of appeals may be reviewed by the Supreme Court by the following methods:

(1) By writ of certiorari granted upon the petition of any party to any civil or criminal case, before or after rendition of judgment or decree;

28 U.S.C. §§ 1331. Federal question; amount in controversy; costs

(a) The district courts shall have original jurisdiction of all civil actions wherein the matter in controversy exceeds the sum or value of $10,000, exclusive of interest and

costs, and arises under the Constitution, laws, or treaties of the United States, except that no such sum or value shall be required in any such action brought against the United States, any agency, thereof, or any officer or employee thereof in his official capacity.

Opposition

Supreme Court, U.S.
FILED
APR 7 1982
ALEXANDER L. STEVAS
CLERK

No. 81-1449

In the Supreme Court of the United States

OCTOBER TERM, 1981

LORA E. LOGE AND ROGER S. LOGE, PETITIONERS

v.

UNITED STATES OF AMERICA, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

BRIEF FOR THE RESPONDENTS IN OPPOSITION

REX E. LEE
Solicitor General

J. PAUL MCGRATH
Assistant Attorney General

ROBERT GREENSPAN
KATHERINE S. GRUENHECK
Attorneys

Department of Justice
Washington, D.C. 20530
(202) 633-2217

QUESTIONS PRESENTED

1. Whether petitioners' claim against the United States for licensing production and approving distribution of poliovirus vaccine made with Sabin strains is barred by the discretionary function exception to the Federal Tort Claims Act, 28 U.S.C. 2680(a).

2. Whether petitioners stated claims for relief arising under the Constitution against government officials sued in their individual capacities for their role in authorizing production and distribution of this poliovirus vaccine.

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LORA E. LOGE AND ROGER S. LOGE, PETITIONERS

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ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

BRIEF FOR THE RESPONDENTS IN OPPOSITION

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. A-1 to A-27) is reported at 662 F. 2d 1268. The opinion of the district court (Pet. App. A-28 to A-49) is reported at 494 F. Supp. 883.

JURISDICTION

The judgment of the court of appeals was entered on November 6, 1981. The petition for a writ of certiorari was filed on February 2, 1982. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. This suit challenges the decision made by federal officials in the early 1960's to authorize the use of live, oral poliovirus vaccine ("Sabin vaccine") in the United States. Unlike the previously used inactivated poliovirus vaccine ("Salk vaccine"), the live Sabin vaccine is capable of producing an immunity to the polio virus not only in those who

receive it but also in persons coming into close contact with the vaccinees (Pet. App. A-4, A-5 to A-6). For that reason and because, unlike the Salk vaccine, it could be administered orally, the Sabin vaccine was seen as a promising means for achieving the virtual eradication of poliomyelitis in the United States.[1] There also exists a risk, however, that in rare cases either a recipient or a contact could develop paralytic poliomyelitis from the vaccine (*id.* at A-4 to A-5).

In 1961, the Secretary of Health, Education, and Welfare, the official then responsible for licensing and regulating the manufacture and distribution of biological products such as vaccines (42 U.S.C. (1958 ed.) 262), established standards for licensing the production of live, oral poliovirus vaccine that were designed to insure its continued safety, purity, and potency. 42 C.F.R. 73.110 *et seq.* (1961). Lederle Laboratories applied for a license to manufacture a "trivalent" vaccine (one containing all three Sabin polio strains), and in June 1963, the Secretary licensed Lederle to produce the vaccine under the trade name "Orimune" (Pet. App. A-4 to A-5).

2. In July 1976, petitioners' son was inoculated with Orimune by their private physician in Fayetteville, Arkansas (Pet. App. A-53 to A-54). One month later, petitioner Lora Loge developed a vaccine-associated case of paralytic poliomyelitis (*id.* at A-6). Petitioners' timely tort claim was denied by HEW in July 1979, and in November 1979 they filed this action for damages in the United States District Court for the Western District of Arkansas (*id.* at A-51).

The amended complaint alleged liability of the United States under the Federal Tort Claims Act (FTCA), 28

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[1]See FDA's Report of the Panel on Review of Viral and Rickettsial Vaccines, *Generic Review of Poliomyelitis Vaccine*, 45 Fed. Reg. 25666 (1980); Salk & Salk, *Control of Influenza and Poliomyelitis with Killed Virus Vaccines*, 195 Science 834, 841 (1977).

U.S.C. 1346(b) (Pet. App. A-50 to A-60) and liability of both the United States and unnamed federal officials in their individual capacities under the Fourth, Fifth, and Ninth Amendments to the United States Constitution (*id.* at A-60 to A-63) for petitioner Lora Loge's paralysis. That condition was alleged to be the result of wrongful acts and omissions in connection with the establishment and administration of the vaccine licensing program pursuant to Section 351 of the Public Health Service Act, 42 U.S.C. 262, and related regulations (Pet. App. A-50 to A-67). In their claims asserted under the FTCA, petitioners alleged (1) that owing to the government's knowledge that contacts of persons immunized with live, oral poliovirus vaccine made from Sabin strains risked contracting poliomyelitis, the government acted negligently in licensing production and permitting distribution of any live strain (*id.* at A-56 to A-57), (2) that, prior to licensing, the government failed, in violation of 42 U.S.C. 262 and certain regulations, properly to test the Sabin strains or the virulence of the virus "shed" by vaccinees (*id.* at A-57 to A-58), and (3) that the government acted negligently in authorizing release of the particular lot of Orimune vaccine (Lederle Lot No. 451-162) from which the dosage administered to petitioners' son was obtained and in approving a package insert that allegedly failed to contain a sufficiently strong warning respecting risks of the vaccine for adult contacts of vaccinees (*id.* at A-58 to A-60).

On the government's motion, the district court dismissed the complaint (Pet. App. A-28, A-49). The court held (*id.* at A-33 to A-36) that no statute or regulation mandated separate testing of the so-called "shed virus" and that the discretionary function exception to the FTCA, 28 U.S.C. 2680(a), barred claims challenging (1) the government's decision not to promulgate regulations requiring such tests, (2) its approval of the package inserts for Orimune, and

(3) its policy decision to license live, oral poliovirus vaccine in the first place. With respect to claims challenging the government's alleged failure to comply with mandatory regulations for the testing of live virus vaccines prior to licensing, the court held (Pet. App. A-37 to A-48) that there was no basis in the applicable state tort law (the law of Arkansas) for such liability and the claims thus failed to state a cause of action under the FTCA. Finally, the court dismissed petitioners' constitutional claims, finding that they had stated no valid cause of action under the Constitution against the unknown government employees (*id.* at A-48 to A-49).

3. The court of appeals affirmed in part and reversed in part (Pet. App. A-1 to A-27). The court upheld (*id.* at A-9 to A-14) the dismissal of claims that the district court had found barred by the discretionary function exception to the FTCA. In so holding, the court of appeals agreed (*id.* at A-11 to A-13) with the district court that there was no mandatory duty to require separate testing of any "shed virus" because such a virus is not a "product" or "dosage" within the meaning of any statute or regulation requiring the performance of tests. With respect to the constitutional claims asserted against unnamed government employees in their individual capacities, the court of appeals agreed (*id.* at A-24 to A-26) with the district court that petitioners' claims cannot be said to arise under the Constitution.

The court of appeals reversed and remanded (Pet. App. A-14 to A-24) with respect to those claims that the district court had dismissed on the ground that analogous claims against private parties were not recognized in Arkansas tort law. The court of appeals characterized the claims in question as allegations that the government had failed (1) "to require the mandatory tests" prescribed in regulations pertaining to vaccine licensing "when Lederle was licensed to

manufacture Orimune in 1963" and (2) "to follow mandatory tests when Lederle's Lot 451-162 was approved" (*id.* at A-14). It concluded that these allegations state a claim for relief under Arkansas law and, because the FTCA provides a tort remedy "where the United States, if a private person, would be liable to the claimant in accordance with the law of the place where the act or omission occurred," (28 U.S.C. 1346(b)), the district court erred in dismissing them.[2]

ARGUMENT

Because of the interlocutory status of this case, review of the issues presented by petitioners would be premature. In any event, the particular holdings of the court of appeals challenged by petitioners are correct and do not conflict with decisions of this Court or any court of appeals. Review is therefore not warranted.

1. The court of appeals has, as noted above, remanded the case to the district court for proceedings in which petitioners may seek to recover damages by proving that the government negligently failed to conduct certain mandatory tests either in connection with the licensing of Orimune or prior to the release of Lot No. 451-162 of the vaccine and that the paralysis of petitioner Lora Loge was a proximate result of such negligence. Should petitioners prove these claims and be made whole by the recovery of damages, their inability to recover damages on another theory for essentially the same injury would be academic. Should judgment

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[2]With respect to the remanded licensing issue, the government will seek to establish in the district court that it complied with all applicable regulations relating to the safety and efficacy of the strains used in Orimune, the vaccine used to inoculate petitioners' child, and the vaccine itself. Those regulations, first codified at 42 C.F.R. 73.110 *et seq.* (1961), are now codified, as subsequently amended, at 21 C.F.R.. 630.1 *et seq.* With respect to the remanded issue pertaining to the release of Lot No. 451-162 of Orimune, the government will similarly seek to show that it acted in compliance with all governing statutes and regulations.

be entered against them and the judgment upheld in the court of appeals, they may seek review in this Court at that time.

2. Citing *Bivens* v. *Six Unknown Federal Narcotics Agents*, 403 U.S. 388 (1971), and *Carlson* v. *Green*, 446 U.S. 14 (1980), petitioners contend (Pet. 11-16) that the decision by government officials to license a vaccine that could, as in the case of petitioner Lora Loge, produce poliomyelitis in a person who comes into contact with a vaccinee violated petitioners' constitutional "rights to privacy and security" and entitled them to recover damages from those officials in an action based directly on the Constitution.[3]

Petitioners do not assert that the federal government required them to have their son inoculated with Sabin vaccine, and they cite no authority for the proposition that a regulatory decision to license the manufacture, or approve the distribution, of a product having both risks and benefits constitutes a violation of the constitutional rights of a person who is injured by the product. Cf. *Procunier* v. *Navarette*, 434 U.S. 555, 565 (1978). This is simply not the kind of direct governmental intrusion into personal lives that may constitute a violation of privacy rights protected by the Constitution, whether in the particular amendments cited by petitioners or "the Penumbra of the Bill of Rights" (Pet. 15). Both courts below therefore correctly held (Pet. App. A-24 to A-26, A-48 to A-49) that petitioners' allegations of negligence in decisions relating to the licensing and release of the Sabin vaccine did not rise to the level of constitutional claims.

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[3]While they do not argue the applicability of particular provisions of the Constitution in the body of their petition, petitioners elsewhere cite (Pet. 2; Pet. App. A-71 to A-72) the First, Fourth, Fifth and Ninth Amendments as the constitutional provisions involved. (Petitioners did not rely on the First Amendment in the courts below.)

3. Petitioners also contend (Pet. 16-20) that the court of appeals erred in holding that the discretionary function exception to the FTCA bars their claims challenging the government's failure to require testing of what petitioners term (Pet. 17) "the 'shed-virus' vaccine."

In making this argument petitioners first challenge (Pet. 17-19) the court of appeals' construction of governmental regulations. This narrow issue was correctly decided by the court of appeals, which carefully examined the language of the regulations in question and determined (Pet. App. A-11 to A-14) that they simply require testing of polio strains to be used in a vaccine and testing of the vaccine itself. As the court explained (*id.* at A-12 to A-13), the "shed virus" vaccine referred to by petitioners was essentially an effect of the licensed vaccine and not itself either a vaccine or a poliovirus strain used in a vaccine.

Petitioners' argument is, therefore, at bottom, an attack on the decision to license a vaccine that may transmit the poliovirus to contacts of vaccinees—a discretionary policy decision of precisely the kind that the discretionary function exception was designed to shield from judicial review in the context of tort litigation. The court of appeals' decision upholding application of that exception to this claim, while permitting petitioners to proceed with their allegations of noncompliance with regulations requiring testing of the polio strains and the vaccine, is consistent with this Court's decision in *Dalehite* v. *United States*, 346 U.S. 15 (1953), and with decisions of other courts of appeals in cases concerning the application of the FTCA to government decisions relating to the licensing or registration of products for public use. See, *e.g.*, *Gelley* v. *Astra Pharmaceutical Products, Inc.*, 610 F. 2d 558, 563 (8th Cir. 1979); *First National Bank in Albuquerque* v. *United States*, 552 F. 2d 370, 374-375 (10th Cir.), cert. denied, 434 U.S. 835 (1977); *Griffin* v. *United States*, 500 F. 2d 1059, 1064 (3d Cir. 1974)

(dictum). See also *Schindler* v. *United States*, 661 F. 2d 552, 555-557 (6th Cir. 1981) (discretionary function exception would apply to any policy-making decisions relating to licensing of vaccine, but issue premature given narrow language of the complaint).

Dalehite involved a claim for wrongful death resulting from the explosion of fertilizer that was produced by private companies for export at the instance, according to the specifications, and under the control of the United States. The fertilizer was known to contain an explosive substance, and the plaintiffs had charged that the government should have avoided any involvement with such an inherently dangerous product or, in any case, should have adopted additional special measures for packing, shipping, and labeling the product. This Court concluded that the approval of such a product, albeit a potentially dangerous one, and the scope of regulation governing its manufacture and distribution fell within the discretion of government officials; accordingly, the Court held that the United States was immune from liability under the FTCA. *Dalehite* clearly controls here, where petitioners challenge a decision within the discretion of the Secretary of Health, Education, and Welfare or his delegees regarding which poliovirus vaccines should be approved for manufacture by private corporations and for use on a voluntary basis in the United States and what kinds of testing of those vaccines should be required.

Finally, petitioners seek to overcome the discretionary function exception by arguing (Pet. 20) that because, in their view, the failure to require a test of the so-called " 'shed-virus' vaccine" is a constitutional violation, the United States is powerless to assert the discretionary function exception to the FTCA. As we have shown above (page 6, *supra*), petitioners' constitutional claims are groundless. In any event, we know of no authority for the proposition

that the sovereign immunity of the United States to actions in damages is overcome by a showing that a tortious act of a government employee constitutes a violation of constitutional rights of privacy. See *Carlson* v. *Green, supra*, 446 U.S. at 28 n.1 (Powell, J., concurring).

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

REX E. LEE
Solicitor General

J. PAUL MCGRATH
Assistant Attorney General

ROBERT S. GREENSPAN
KATHERINE S. GRUENHECK
Attorneys

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